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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/041,975	03/13/98	ALIZON M	2356.0011-06

HM12/0706

FINNEGAN HENDERSON FARABOW
GARRETT AND DUNNER
1300 I STREET NW
WASHINGTON DC 20005-3315

EXAMINER	
PARKIN, J	
ART UNIT	**PAPER NUMBER**
1648	16

DATE MAILED: 07/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applic[illegible]s)
09/041,975	Alizon et al.
Examiner	**Group Art Unit**
Jeffrey S. Parkin, Ph.D.	1641

☒ Responsive to communication(s) filed on *9 Jul 1999*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *23-38* is/are pending in the application.

Of the above, claim(s) *26-38* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *23-25* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

Detailed Office Action

Continued Prosecution Application

1. The request filed on 26 April, 2000, for a Continued Prosecution Application (CPA) under 37 C.F.R. § 1.53(d) based on parent Application No. 09/041,975 is acceptable and a CPA has been established. No amendments or arguments accompanied the filing.

Status of the Claims

2. Applicants are reminded of the restriction requirement set forth in Paper No. 7. Since this application is a CPA filed pursuant to 37 C.F.R. § 1.53(d) based upon parent Application No. 09/041,975 and does not contain an indication that a shift in election is desired, the election made in the prior application is being carried over (see M.P.E.P. ¶ 201.06(d)). Accordingly, claims 26-38 have been withdrawn from further consideration by the Examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

35 U.S.C. § 112, First Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 23-25 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In*

re Rasmussen, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claimed invention is broadly directed toward purified HIV-1 variants that differ genetically in the *gag*, *pol*, and *env* coding regions from three known HIV-1 prototypes (e.g., IIIB, BRU, and ARV-2) by the specified amounts (e.g., 3.4% in Gag, 3.1% in Pol, and 13.% in Env). As such, the claim language encompasses a large genus of viruses. Applicants previously argued that the isolation and characterization of at least two HIV-1 isolates (e.g., MAL and ELI) is described in the application which provides sufficient support for the claimed invention. It was further argued that the disclosure would reasonably convey to the skilled artisan that the Applicants were in possession of a group of evolutionarily diverse viruses. Applicants' arguments were thoroughly considered but deemed to be nonpersuasive for the reasons of record previously set forth (Paper Nos. 9 and 13) and as further elaborated below.

Contrary to applicants' assertion, the disclosure only describes the molecular cloning and characterization of a single novel HIV-1 isolate, designated LAV-1_{MAL} ("this new virus is hereinafter generally referred to as "LAV_{MAL}".", "Recovery and purification of the LAV_{MAL} virus", "Primary restriction enzyme analysis of LAV_{MAL} genome was done", "LAV_{MAL} was isolated from the peripheral blood lymphocytes", "Figures 7A-7I show the complete cDNA sequence of LAV_{MAL} of this invention.", pages 3, 7, 8, 18, and 22, respectively). A molecular clone was identified and it's nucleotide sequence ascertained. Applicants used the nucleotide sequence of this molecular clone to compare it to other known HIV-1 isolates to assess the genetic relatedness of different isolates (see Figures 1-6). However, while nucleotide sequence comparisons with known viral isolates were performed, the disclosure fails to provide any evidence suggesting that additional HIV-1 isolates, containing the specific claimed limitations, were isolated and

purified. Although vague reference was made to "variants of the new virus" on page three of the specification (first paragraph), the disclosure fails to provide any guidance pertaining to the genotypic and phenotypic properties of any of these purified variants. Moreover, the disclosure is clearly directed toward a novel HIV-1 isolate, designated LAV_{MAL}, as set forth throughout the disclosure (e.g., SUMMARY OF THE INVENTION, pages 2-6; EXPERIMENTAL PROCEDURES, pages 18 and 19; bridging paragraph, pages 22 and 23; etc.). Legal precedence also dictates that the disclosure of a single species, in combination with generic methods for it's isolation, does not provide sufficient written description for the broad genus *per se*. *University of California* v. *Eli Lilly* and *Co.*, 43 U.S.P.Q.2d 1398 (C.A.F.C. 1997). *Fiers* v. *Revel*, 984 F.2d 1164, 1171, 25 U.S.P.Q.2d 1601, 1606 (Fed. Cir. 1993). *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.* 18 U.S.P.Q.2d 1016-1031 (C.A.F.C. 1991). Thus, the skilled artisan would reasonably conclude that while applicants were in possession of a purified HIV-1 isolate designated LAV_{MAL}, they were not in possession of any other HIV-1 variants, particularly those with the claimed genetic differences. Moreover, it would appear to the skilled artisan that applicants are simply trying to retroactively claim subject matter which was neither contemplated or described. Thus, the rejection is hereby maintained.

35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

35 U.S.C. § 103(a)

6. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

8. Claims 23-25 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Myers *et al.* (1990). Applicants' arguments have been previously considered. As noted *supra*, this application fails to provide an adequate written description of the claimed invention and priority cannot be extended under 35 U.S.C. § 119 or 120. Accordingly, the following art rejection is maintained. Myers *et*

al. (1990) provide the complete nucleotide sequence of a novel purified HIV-1 isolate designated Z2Z6. This isolate is genetically related to the HIV-1 isolates ELI and MAL and appears to be only distantly related to the isolates BRU, IIIB (or HXB2), and ARV-2 (SF-2). Nucleotide sequence and amino acid analysis demonstrated that this isolate appears to vary from the aforementioned prototypical isolates BRU, IIIB, and ARV-2 by at least 3.4%, 3.1%, and 13.0% in the *gag*, *pol*, and *env* coding regions, respectively. Thus, this isolate appears to meet all the limitations of the claimed invention. Moreover, because of the close genetic relatedness between Z2Z6 and the isolates ELI and MAL, one of ordinary skill in the art would reasonably expect nucleic acid probes and antibodies specific for MAL to also recognize Z2Z6 nucleic acids and antigens.

Finality of Office Action

9. All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 C.F.R. § 1.53(d) and could have been finally rejected on the grounds of art and record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL**, even though it is a first action after the filing under 37 C.F.R. § 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). **A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE**

STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Correspondence

10. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648.**

11. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

12. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

30 June, 2000

LAURIE SCHEINER
PRIMARY EXAMINER